K000511

MAR 13 2000

Special 510(k)
Summary of Safety and Effectiveness
ArthroCare Corporation
ArthroCare® Orthopedic Electrosurgery System

Manufacturer:	ArthroCare, Corporation 595 North Pastoria Avenue Sunnyvale, CA 94086-2916
Establishment Registration Number:	2951580
Contact Person:	Bruce Prothro Vice President, Regulatory Affairs and Quality Assurance
Date Prepared:	February 15, 2000

Device Description

Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)
Trade Name:	ArthroCare® Orthopedic Electrosurgery System
Generic/Common Name:	Electrosurgical Device and Accessories

Predicate Devices

ArthroCare Orthopedic Electrosurgery System	K992581; cleared on December 9, 1999 K000044; cleared on February 1, 2000

Intended Use

The ArthroCare Orthopedic Electrosurgery System is indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in orthopedic, arthroscopic, and spinal procedures.

Product Description

The ArthroCare Orthopedic Electrosurgery System is a bipolar, high frequency electrosurgical system. The System consists of three components: an electrosugical generator called the Controller, the reusable Cable, and the disposable Wand.

Substantial Equivalence

This special 510(k) proposes a modification in performance specifications for the Wand components of the ArthroCare Orthopedic Electrosurgery System, which was previously cleared under K992581, on December 9, 1999. The technology, principle of operation and the intended use of the entire System remain the same as in the original cleared 510(k). The materials remain the same as described in K992581 and K000044.

Summary of Safety and Effectiveness

The ArthroCare Orthopedic Electrosurgery System modified Wands, described in this submission, are substantially equivalent to the predicate, unmodified Wands. The proposed modifications in performance specifications are not substantial changes or modifications, and do not significantly affect the safety or efficacy of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 2000

Mr. Bruce Prothro
Vice President, Regulatory Affairs and
Quality Assurance
ArthroCare Corporation
595 North Pastoria Avenue
Sunnyvale, California 94086-2916

Re: K000511
Trade Name: ArthroCare Orthopedic Electrosurgery System
Regulatory Class: II
Product Code: GEI
Dated: February 15, 2000
Received: February 16, 2000

Dear Mr. Prothro:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications Statement

Device Name: ArthroCare® Orthopedic Electrosurgery System
510(k) Number: K000511

Indications for use:

The ArthroCare Orthopedic Electrosurgery System is indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in orthopedic, arthroscopic, and spinal procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000511